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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,904	03/03/2000	JOHN R. SNYDER	3220-66107	9526

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EXAMINER	
HELMER, GEORGIA L	

ART UNIT	PAPER NUMBER
1638	10

DATE MAILED: 01/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/486,904	SNYDER ET AL.	
	Examin r	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 20-23* is/are pending in the application.

4a) Of the above claim(s) 10-19 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 9 and 20-23 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3 March 01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

09/486,904

DETAILED ACTION

Restriction Election

1. The Office acknowledges the receipt of restriction election, Paper No. 9, filed November 20, 2001. Applicant elects Group III, claim 9, with traverse, stating that the claims of Groups III – V represent different stages of a continuing process and are not distinct inventions. Applicant's traversal is not persuasive because these claims are directed to different methods for biosynthetically producing commercially valuable compounds, whereby each of the methods use different starting materials, have different steps and use different reagents. Claims 9-14 and 20-23 are pending. Claims 10-14 are nonelected. Claims 9 and newly added claims 20 – 23 are examined in the instant application. This restriction is made FINAL.

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because benefit to a provisional application should be listed under 35 USC 119(e), and not under 35 USC 120.

Information Disclosure Statement

3. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 4, is attached to the instant Office action.

Drawings

4. This application has been filed with drawings which have been approved by Office draftsperson.

Claim Rejections - 35 USC § 112, second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 20 – 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 9 and 20-23 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: culturing plant cells so as to produce a fertile transgenic plant from plant cells, self-pollinating said transgenic plant; expressing the recombinase in the plant; and producing commercially valuable compounds. The recited method of Claim 9, without the above steps, is lacking essential elements.

In claim 9, "biosynthetically producing" is unclear. Does this mean making a biological compound or having a biological organism make the compound? "Biologically detrimental" is unclear because to whom or to what the compound is detrimental is

unspecified. Is the compound detrimental to all biological organisms which come in contact with the compound, or is the compound detrimental to the organism expressing the compound? It is suggested changing the language "becomes" operably linked to "is" operably linked. Clarification and/or correction are required.

Claim Rejections - 35 USC § 112, first paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9 and 20 – 23 are rejected under 35 U.S.C. 112, first paragraph. The specification while being enabling for a method which includes the steps of culturing plant cells so as to produce a fertile transgenic plant from plant cells, self-pollinating said transgenic plant; expressing the recombinase in the plant; and producing commercially valuable compounds, does not reasonably provide enablement for the method without these steps. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The recited method of Claim 9, without the above steps, is lacking essential elements. In order to produce transgenic plant from plant cells, various steps of in vitro culture are needed. See Birch, Annu. Rev. Plant Physiol. Plant Mol. Biol. 1997, 48:297-326; Figure 1, p 304 (U). In order to produce a homozygous transgenic plant, the plant must be self-pollinated, rather than cross-fertilized. Producing commercially valuable compounds using Applicant's

invention would not occur in the absence of a recombinase being expressed in the plant. The recombinase must be expressed in the plant for this production to occur. The idea of temporality need to be stated such that the recominbase is expressed followed by excision of the blocking sequence and that then the detrimental compound is expressed. Accordingly, without the inclusion of these essential steps, the claims are not fully enabled.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 9 and 20-22 are rejected under 35 USC 102 (b) as being anticipated by Odell et al, US patent # 5,658,772, filed 27 July 1994, issued 19 August 1997 (AA). Re Claim 9, 20-22, Odell et al teach the production of a plant producing of a biologically detrimental compound (column 14, lines 10-16) by a promoter, a blocking sequence flanked by a pair of directly repeated site specific recombination sequences, and a structural gene coding for the biologically detrimental compound wherein the structural gene becomes operably linked to the promoter only after removal of the blocking sequence (column 14, lines 15-17). Odell further teaches removal of the blocking sequences flanked by directly repeated site-specific recombination sequences in the presence of the recombinase gene (column 14, lines 23-26). Odell teaches the use of constitutive promoters (column 7, 39-45), the production of homozygous plants and genetic crosses of homozygous plants (columns 29 & 30, lines 67 and 1-5 respectively). Odell also teaches the extractions of biological compounds from plant tissue (Column 15, lines 8-10). Accordingly, Odell anticipates the present invention.

Claim R jections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9 and 20 – 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilby, NJ et al; (1995) Plant Journal 8: 637-652 (AR), in view of Odell et al (AA) and Kilby, NJ et al (1993) Trends in Genetics, 9: 413-421 (V). Kilby (1995) teaches introducing into plant cells a DNA construct comprising a promoter, a blocking sequence, and a structural gene, where the blocking sequence is flanked by a pair of directly repeated site-specific recombination sequences wherein the structural gene is operably liked to the promoter only after the removal of the blocking sequence (Figure 2, page 639). Kilby does not teach biological detrimental compounds. Odell et al teach detrimental compounds (column 14, lines 15, 25 and 26). The toxicity of the detrimental biological compound itself provides motivation for blocking expression until the desired time. Kilby (1993) (pg 420) suggest the strategy of gene activation only after removal of a blocking sequence as being particularly useful for expressing potentially harmful genes. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the strategy of expressing a biologically detrimental compound only after removal of a blocking sequence. One skilled in the art would have

been motivated to generate the claimed invention with a reasonable expectation of success.

Odell further teaches the site-specific recombination system of Cre recombinase and lox site specific recombination sequences. It is know in the art that the Cre/lox and the FLP/frt site-specific recombination systems (composed of the recombinase enzyme—either Cre of FLP, and their cognate recombination target sites—either lox or frt respectively) are functional equivalents (see Kilby et al, 1993, (V)). These are known prior art systems for addressing the same problem. Accordingly, the use of the Cre/lox or the FLP/frt recombination system is a matter of design choice well within the means of one of ordinary skill without any surprising or unexpected results.

Remarks

9. No claim is allowed.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

January 28, 2002
Georgia L. Helmer Ph.D.
Patent Examiner
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703-308-7023

PHUONG T. BUI
PRIMARY EXAMINER